Geratherm® Respiratory

Ergostik

Serial numbers: xx|8|201|yyy and 2201xxxxx

Instruction for Use

Version: 13

Release date: 02 August 2022

Please read carefully and store in a place which is always accessible for future consultation!

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Foreword

Thank you for purchasing a medical device from Geratherm® Respiratory GmbH. Ergostik is part of our product family with solutions for cardiopulmonary function diagnostics which are operated using the common software platform BLUE CHERRY®. This means that you have the option of optimising the working processes in your practice using the networked application of further products from Geratherm® Respiratory GmbH, and to benefit from the simple use of our products.

1 General Information

All our medical devices are manufactured and tested in accordance with certified quality standards. This means that Ergostik fulfills the regulatory requirements for medical devices (class IIa).

This IFU is a component of the product in accordance with DIN EN ISO 60601-1. It should make it easier to familiarise yourself with Ergostik, as well as give you instructions about its intended use and safe operation.

This IFU has been written for healthcare professionals who are qualified to perform cardiopulmonary exercise tests.

The basic prerequisite for safe working with the Ergostik is to follow all the safety instructions given.

In addition to the notes in this IFU, the local accident prevention regulations and the national industrial safety regulations apply.

Read this IFU carefully and in its entirety before using Ergostik. For future reference, keep them in the immediate vicinity of the medical device, ready at hand for the user / operator and accessible at all times!

Please refer to the separate IFU of the BLUE CHERRY® software platform for pulmonary function diagnostics.

If, in spite of careful reading of this IFU, you require more information, please contact your specialist retail partner on site. You can obtain the contact details via a form provided by the manufacturer at www.geratherm-respiratory.com/login/.

1.1 Abbreviations

The following simplified style of writing and abbreviations are used hereinafter to make this IFU easier to read.

Instructions for Use	→ IFU
Geratherm® Respiratory GmbH	→ Manufacturer
Medical specialist personnel	→ User(s)
Personnel instructed in cleaning/ maintenance work	→ Operator(s)

1.2 Explanations

For the safety of your patients, for your personal safety and to avoid damage to property, observe the meaning of the following explanations of symbols. These are divided into hazard levels. If several severity levels occur at the same time, the warning note for the highest level is always used.

The safety instructions are presented in accordance with DIN ISO 3864 following ANSI Z535.4 (American National Standards Institute).

DANGER	Indicates a directly hazardous situation. Not observing and not avoiding the situation will lead to death or severe injuries. The signal word DANGER is only used for extreme situations.
WARNING	Indicates a possibly hazardous situation. Not observing and not avoiding the situation may lead to death or severe injuries.
CAUTION	Indicates a possibly hazardous situation. Not observing and not avoiding the situation may lead to minor or moderate injuries.
Attention	Not observing this warning information may lead to faults or malfunctions of the Ergostik or may indicate that something in its environment may be damaged.
	Indicates places in the IFU which are relevant to the current topic but do not present any danger, or which simplify your handling of the Ergostik.

1.3 Symbols

Symbols displayed in this IFU, on the medical device itself and/or on its packaging are standardised symbols.

Symbol	Explanation
	**Follow the instructions for use!**
	**Applied part from type BF corresponding to DIN EN 60601-1** The applied part is in direct contact with the patient (BF: Body Floating). In order to comply with the limit value for the patient leakage current, the applied part is insulated from earth.
	**Device of protection class II** (safety measure against touching) Protection by double or reinforced insulation For the prevention of electric shock.
	**Only use indoors!**
IP20	**Protection type (safe environmental conditions)** IP2x: Protection of enclosure against ingress of solid foreign objects with a diameter greater than or equal to 12.5 mm and access to hazardous parts with finger. IPx0: No protection of enclosure against harmful ingress of water.

Symbol	Explanation
	**Do not dispose of the device along with general household waste!** It must be disposed of in a proper and correct manner via the distributor. By marking a device with this symbol, the manufacturer also declares that he fulfills all the requirements of the law on the distribution, return and environmentally friendly disposal of electrical and electronic devices. (Rechargeable) batteries must be taken to a central collection point for used batteries or to the manufacturer.
	**For single use only!** This symbol does not refer to the Ergostik itself, but to the consumable items used in connection with it. This is applied to the respective packaging and must be observed.
	**Batch number** This symbol identifies the batch or lot code given by the manufacturer. The code is placed adjacent to the symbol.
	**Serial number** This symbol identifies the serial number given by the manufacturer.
	**Catalog number** This symbol identifies the catalog number given by the manufacturer.
	**Manufacturer** This symbol identifies the manufacturer of a product.
	**Date of manufacture** This symbol indicates the date on which a product is manufactured.

Symbol	Explanation
CE 0494	**Conformity mark** This symbol indicates conformity with health, safety and environmental protection standards for products sold within the European Economic Area (EEA). The additional four-digit number identifies the Notified Body involved in the conformity evaluation procedure of this product. In this case 0494 identifies SLG Prüf- und Zertifizierungs GmbH as Notified Body.
	**Caution, non-ionizing electromagnetic radiation** Precautions must be taken to avoid an unexpected effect of non-ionizing radiation.
	**General warning symbol** Warning of a hazardous area.
	**Fragile, handle with care** The package contains a product that must be handled with appropriate care to prevent damage during transport and storage.
	**Keep away from rain** The package contains a product that must be protected from moisture during transport and storage.
	**Temperature limitation** The product can be safely transported, stored or operated within the specified temperature range.
	**Humidity limitation** The product can be safely transported, stored or operated within the specified humidity range.

Symbol	Explanation
	**Atmospheric pressure limitation** The product can be safely transported, stored or operated within the permissible atmospheric pressure.

1.4 Copyright

1.5 Limitation of Liability

The manufacturer emphasises the creation of accompanying documents for his products. Despite careful checking, errors or inaccuracies in this document version cannot be completely ruled out. The liability of the manufacturer for direct or indirect damages arising in connection with the present documentation is excluded to the extent permitted by law. Technical or content information in this document is subject to change at any time and without notice. Should any questions arise, please contact your authorised specialist retailer or the manufacturer directly.

2 Conditions of Use

Any other use of Ergostik which is not described in this IFU is deemed improper use. The responsible organisation of Ergostik alone is liable for any direct or indirect damage resulting from not adhering to these conditions.
They are then solely responsible for the fulfillment of the basic requirements of the medical device and assumes complete product liability for the whole system.

2.1 Intended Purpose

The medical device Ergostik is a PC-based measuring device used to determine physical ability by measuring gas exchange. The examination involves an analysis of the interplay between a patient's heart, circulatory system, breathing and metabolism whilst their body is being put under a defined load. The test subject is put under load whilst on an ergometer. Their heart rate, breathing rate, respiratory minute volume, oxygen intake and carbon dioxide output is continually recorded throughout the process.
The Ergostik consists of a case with integrated electronics used to determine ventilation, as well as to analyze oxygen and carbon dioxide levels. It is connected to a computer via an integrated USB interface. A 12 V power supply is used. The tried and tested Ergoflow flow sensor is used to measure flow.
The measurement device is supplied with BLUE CHERRY® software. The standard version contains CPET, spirometry and flow / volume measurements, as well as pre / post examinations and trend analysis. The software contains a database for patient information and measurement results. The modular design of both software and hardware allows additional measurement options to be incorporated, such as MVV or SPO2.

Examination	Required option
Bronchoprovokation	Provokation (REF 403680)
Resting Energy Expenditure / Resting Metabolic Rate	REE (REF 526143)

You can find more information in:

- IFU Spirometry
  for carrying out the examination
- IFU BLUE CHERRY®
  for the general operation of the software and carrying out the examination

2.1.1 Indication

The Ergostik can be used for cardio-pulmonary (exercise) tests for diagnosis, follow-up, screening and severity assessment of pulmonary diseases. These include in particular:

Evaluation of exercise intolerance

Unexplained dyspnea

Evaluation of patients with cardiovascular diseases

Evaluation of patients with respiratory diseases

- Chronic obstructive pulmonary disease
- Interstitial lung disease
- Chronic pulmonary vascular disease
- Cystic fibrosis
- Exercise-induced bronchospasm

Preoperative assessment

- Preoperative assessment for lung cancer resection surgery
- Surgery to reduce lung volume
- Evaluation for lung or heart-lung transplantation
- Preoperative evaluation of other procedures
- Prescription of pulmonary rehabilitation exercises

Prescription of pulmonary rehabilitation exercises

Assessment of the impairment / disability

2.1.2 Contraindication and Side Effect

2.1.2.1 Contraindications

The following contraindications apply to ergometric examinations:

Contraindications	Absolute	Relative
Acute myocardial infarction (3–5 days)	X	
Unstable angina	X	
Uncontrolled arrhythmias	X	
Syncope	X	
Active endocarditis	X	
Acute myocarditis or pericarditis	X	
Symptomatic severe aortic stenosis	X	
Uncontrolled heart failure	X	
Acute pulmonary embolus or pulmonary infarction	X	
Thrombosis of lower extremities	X	
Suspected dissecting aneurysm	X	
Uncontrolled asthma	X	
Pulmonary edema	X	
Respiratory failure	X	
Room air desaturation at rest <= 85 %	X	
Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by exercise	X	
Mental impairment leading to inability to cooperate	X	X
Left main coronary stenosis or its equivalent		X
Moderate stenotic valvular heart disease		X
Severe untreated arterial hypertension at rest (200 mm Hg systolic, 120 mm Hg diastolic)		X
Tachyarrhythmias or bradyarrhythmias		X

High-degree atrioventricular block	X
Hypertrophic cardiomyopathy	X
Significant pulmonary hypertension	X
Advanced or complicated pregnancy	X
Electrolyte abnormalities	X
Orthopedic impairment that compromises exercise performance	X

As the transitions between absolute and relative contraindication can be fluid in the assessment, the assertion of a physician should be regarded as binding.
(Source: American Thoracic Society, American College of Chest Physicians. ATS/ACCP Statement on cardiopulmonary exercise testing. 2003. Am J Respir Crit Care Med. 167:211–277.)

The following contraindications apply to spirometry examinations:

Contraindications
Due to increases in myocardial demand or changes in blood pressure • Acute myocardial infarction within 1 week • Systemic hypotension or severe hypertension • Significant atrial / ventricular arrhythmia • Noncompensated heart failure • Uncontrolled pulmonary hypertension • Acute cor pulmonale • Clinically unstable pulmonary embolism • History of syncope related to forced expiration / cough
Due to increases in intracranial / intraocular pressure • Cerebral aneurysm • Brain surgery within 4 weeks • Recent concussion with continuing symptoms • Eye surgery within 1 week
Due to increases in sinus and middle ear pressures

• Sinus surgery or middle ear surgery or infection within 1 week
Due to increases in intrathoracic and intraabdominal pressure • Presence of pneumothorax • Thoracic surgery within 4 weeks • Abdominal surgery within 4 weeks • Late-term pregnancy
Infection control issues • Active or suspected transmissible respiratory or systemic infection, including tuberculosis • Physical conditions predisposing to transmission of infections, such as hemoptysis, • significant secretions, or oral lesions or oral bleeding

Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.
(Source: Graham, B. L. et al. 2019. Standardization of Spirometry 2019 Update. Am J Respir Crit Care Med Vol 200, Iss 8, pp e70–e88.)

2.1.2.2 Side Effects

If there are no contraindications and the examination is carried out in accordance with the descriptions in the IFU, cardio-pulmonary exercise testing is a safe examination, but in rare cases (1 per 10,000 examinations) serious cardiac incidents and death (2-5 per 100,000 examinations) can occur. Therefore, the following safety measures must be observed when conducting cardio-pulmonary exercise tests:

- Presence of a physician for timely detection and assessment of termination criteria (see table below)
- Presence of emergency equipment (defibrillator, emergency medication)
- Availability of emergency medically trained personnel for assistance

The following side effects may also occur:

Side effect / Frequency	Rules of conduct
Exhaustion / Frequent	Stopping the exercise after medical assessment.
Shortness of breath / Frequent	Stopping the exercise after medical assessment.
Chest pain / Frequent	Stopping the exercise after medical assessment, monitoring of the patient for cardiac events and, if necessary, treatment of these.
Cardiac arrhythmias / Frequent	Stopping the exercise after medical assessment, monitoring of the patient for cardiac incidents and treatment of these if necessary.
Bronchospasm / Rare	Stopping the exercise after medical assessment, monitoring of the patient after the examination and administration of a bronchodilator if necessary.

Syncope / Rare	Treatment and initiation of emergency medical measures if necessary.

Cancellation Criterion	Absolute	Relative
ST-Depression ≥ 3 mm	X	
ST-Elevation ≥ 1 mm	X	
Blood pressure drop > 10 mmHg (compared to initial blood pressure) with signs of myocardial ischemia (angina pectoris, ST Depression)	X	
Moderately severe angina pectoris symptoms	X	
Severe dyspnoea	X	
Clinical signs of low perfusion (cyanosis)	X	
Persistent (duration > 30 sec.) ventricular tachycardia	X	
Exhaustion of the patient	X	
Technical problems (defective ECG registration...)	X	
Hypertensive dysregulation (Rrsyst 230-260 mmHg, Rrdiast ≥ 115 mmHg)		X
Blood pressure decrease > 10 mmHg (compared to the initial blood pressure) without signs of myocardial ischemia (no angina pectoris, no ST depression)		X
Polymorphic extrasystole, pairs (2 consecutive VES), volleys (≥ 3 consecutive VES)		X
Supraventicular tachycardia		X
Bradyarrhythmias		X
Conduction Disorders		X
Occurrence of conduction disorders (higher grade AV block, thigh block)		X
Increased angina pectoris symptoms		X

As the transitions between absolute and relative contraindication can be fluid in the assessment, the assertion of a physician should be regarded as binding.
(Source: Deutsche Gesellschaft für Kardiologie. 2000. Leitlinien zur Ergometrie. Z Kardiol. 89:821–837.)

2.1.3 Definition of the Groups of People

Groups of people named in this IFU are defined as follows:

Manufacturer
specifies all measures to ensure the safe and proper handling and application of Ergostik. They are responsible for instructing the operator in relation to this via the corresponding specialist retail partner.

Responsible Organisation
is any natural or legal person who is responsible for the operation of the health institution where Ergostik is used by their employees (users).

User
is a medically trained specialist who is familiar with cardio-pulmonary exercise tests, who uses Ergostik on the patient after verifiable instruction by the responsible organisation and / or is responsible for rectifying faults to the Ergostik, as well as its calibration.

Users must be aware of the clinical meaning and, for example, be a physician, physician's assistant, assistant or trained maintenance personnel with basic electrical or mechanical training. The user is able to identify, assess and, in the best case, to avoid possible hazards when using Ergostik.
Trainee medical specialists must also be supervised in addition to receiving training in how to use Ergostik.

Operator
is a person who has received instruction on cleaning Ergostik by a medically trained specialist.

Patient
is a person undergoing medical treatment (check-up, initial diagnosis as well as progress / treatment monitoring) to assess their pulmonary exercise tolerance. The persons can be adults without an age limitation as well as children form 4 years of age. A requirement for carrying out the examination is the ability to follow the instructions of the user.

2.2 Intended Use

Ergostik can be operated independently as a non-stationary device or in combination with all other Geratherm® Respiratory GmbH products via the universal software BLUE CHERRY®. (see chap. 4.1.3 “System Construction and Electrical Safety”).

In all cases, the Ergostik is only intended for use in closed, pleasantly temperature-controlled (19 °C – 25 °C) rooms in a clinical area.

In the respective room, there must be neither flammable or explosive gases, nor magnetic fields (e.g. MRI).

The following applies in general: The installation of Ergostik is only deemed safe and in line with intended use when this is carried out in accordance with the details in chap. 12.2 “Installation and Operating Conditions”.

The responsible organisation must ensure that only medically trained specialist personnel (see chap. 2.1.3 “Definition of the Groups of People”) operates Ergostik. Personnel must demonstrably have been given training in the function of Ergostik. This also includes a complete study of this IFU.

The manufacturer has determined the expected service life (see chap. 11.1 "Expected Service Life") and the maintenance work required for this (see chap. 8 "Servicing / Maintenance").
The Ergostik may only be used for the duration of its service life if the specifications are observed.
Any changes to Ergostik, in particular unauthorised modifications, are prohibited.

The Ergostik is not intended for the control of vital physiological parameters where the nature of the change could lead to immediate danger to the patient, e.g. changes in heart function, respiration or central nervous system activity.

Any other than the described use is deemed improper use. The responsible organisation of Ergostik alone is liable for any damage resulting from not adhering to these conditions.

Intended use also includes complying with all further information and instructions in this IFU, without exception.

Attention	Electromagnetic compatibility (EMC) in accordance with DIN EN 60601-1-2:2016-05; VDE 0750-1-2:2016-05; IEC 60601-1-2:2014. See chap. 12.4 “Electromagnetic Compatibility / EMC Guidelines”. Ergostik is suitable for use in all institutions including those in residential areas and those which are directly connected to the public supply network which also supplies buildings used for residential purposes.

2.2.1 Original Spare Parts / Accessories / optional Expansions

Intended use also includes using prescribed original spare parts, accessories and expansions in constructing the system.

Only the components stated in the following are deemed tested and approved, as products by the manufacturer of Ergostik.

The installation or use of other products can, under certain circumstances, negatively change constructive prescribed properties of Ergostik and, in the worst case, impair the safety of the patient, operator and / or third parties.

The manufacturer assumes no liability for such consequences. All warranty claims shall expire.

⚠ WARNING	Possible danger to life. Reason: **Cross contamination.** Therefore: • Ensure that the used components are undamaged and that you are working in a careful way! • Do not use consumable articles with a limited life span after their use-by date has been expired!
⚠ CAUTION	Possible physical injury. Reason: **Device damage as well as impurities / contamination due to improper handling of components.** Therefore: • Protect separately stored components, accessories and consumable items from unauthorised access! • Observe the storage conditions stipulated by the manufacturer!

2.2.1.1 Original Spare Parts / Accessories

The following components can be purchased via specialist retail partners.

You will find:

- A list of specialist retail partners as an insert in this IFU or in your medical device book, as well as the most updated version at www.geratherm-respiratory.com/login/
- Instructions on safe system construction in chap. 4.1.3 of this IFU
- Further information about Ambistik in the separate IFU Ambistik

Component	Description / name	Supply scope in units	REF
	**Ergostik** ➢ Cardiopulmonary exercise system for accurate measurement of flow, O_2 and CO_2. ➢ USB 2.0 based desktop device.	01	979119 [old:40.400]
	**BLUE CHERRY® Media Pack** ➢ Modular and intuitive Windows based diagnostic software platform for pulmonary function	01	598197 [old:10.500]

Component	Description / name	Supply scope in units	REF
	**Ergoflow** ➢ Re-useable lightweight Flow Sensor for use with Ergostik, PFTstik, Bodystik and Diffustik device.	03	139094 [old:10.600]
	**Silicone Mouthpiece** ➢ Silicone rubber bite mouthpiece for use with Ergoflow sensors.	01	275865 [old:10.816]
	**Softclip** ➢ Disposable noseclip for lung function tests. ➢ Made of soft, skin-friendly foam for best wearing comfort ➢ One size	03	787158 [old:10.200]
	**Exercise Tube Set incl. Ergoclip, 2 m** ➢ Flow and gas connection Tube set with permapure tube for moisture equilibration, hydrophobic minifilter and Ergoclip adapter for Ergoflow.	02	830971 [old:40.424]
	**Calibration Tube** ➢ Tube 1,5 m with black Luer connector for gas calibration of Ergostik. ➢ Outer diameter 4 mm.	01	862229 [old:40.421]

Component	Description / name	Supply scope in units	REF
	**Power Supply, 12 V** ➢ Medical grade 12 V power supply.	01	628020 [old:10.841]
	**Power Cord, CEE 7/16, C7 (IEC 60320, EU)** ➢ Power cord with European plug for use with power supply (12 V).	01	142297 [old:10.838]
	**USB-Connection Cable, 1.8 m** ➢ USB-connection cable (male A and male B) to connect USB based devices to PC.	01	362803 [old:10.820]
	**Silicone Adapter, Small** 28 mm x 2 mm x 50 mm ➢ Silicone adapter size small used for Ergoflow, PFTstik, Bodystik and Diffustik to connect to calibration syringe.	01	919774 [old:10.831]
	**Ambistik** ➢ USB 2.0 Ambient conditions module for accurate online BTPS conditions. ➢ Continuous measurement of ambient temperature, pressure and humidity. ➢ Runs on Windows based diagnostic software platform BLUE CHERRY®.	01	634247 [old:40.300]

Component	Description / name	Supply scope in units	REF
	**Pressure Regulator GM, Calibration Gas (DEU)** ➢ For bottles with connector DIN477-1, 1990 No. 14 (External thread, Left-hand thread, M 19 x 1.5)	normally not included but recommended!	862520 [old: 940288]
	**Pressure Regulator GM, Calibration Gas (CHE/FRA)** ➢ For bottles with connecotor DIN477-1, 1990 No. 6 (External thread, Right-hand thread, W 21.80 x 1/14”)	normally not included but recommended!	672472 [old: 623668]
	**Pressure Regulator GM, Calibration Gas** ➢ For bottles with connector UNI 11144:2005 No. 5. (Inner thread, Right-hand thread, W 21,7 x 1/14")	normally not included but recommended!	777222 [old: 444513]

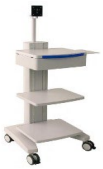
2.2.1.2 Optional Expansions

The following add-ons can be purchased via specialist retail partners.

You will find:

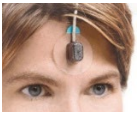
- A list of specialist retail partners as an insert in this IFU or in your medical device book, as well as the most updated version at www.geratherm-respiratory.com/login/
- Instructions on safe system construction in chap. 4.1.3 of this IFU

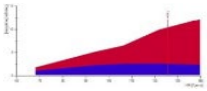
- Further information about Ambistik in the separate IFU “Ambistik”

Component	Description / name	REF
	**Exercise Cart** ➢ Base frame, drawer block, 1 storage shelf, 2 monitor holder, 2 Liter gas bottle holder and 1 Universal bottom storage shelf incl. safety transformer and multiple sockets.	445929 [old:10.900]
	**Calibration Syringe** ➢ Precision calibration instrument for calibration of flow or volume based systems. ➢ 3 Liter volume (nonadjustable). ➢ Comes together with adapter for Spiraflow, Ergoflow and Blueflow.	608220 [old:10.801]
	**Pressure Regulator GM, Calibration Gas (DEU)** ➢ For bottles with connector DIN477-1, 1990 No. 14 (External thread, Left-hand thread, M 19 x 1.5)	862520 [old: 940288]
	**Pressure Regulator GM, Calibration Gas (CHE/FRA)** ➢ For bottles with connecotor DIN477-1, 1990 No. 6 (External thread, Right-hand thread, W 21.80 x 1/14”)	672472 [old: 623668]
	**Pressure Regulator GM, Calibration Gas** ➢ For bottles with connector UNI 11144:2005 No. 5. (Inner thread, Right-hand thread, W 21,7 x 1/14")	777222 [old: 444513]

Component	Description / name	REF
	**Pressure Regulator, Calibration Gas (DEU)** No longer available ➢ Pressure regulator for exercise gas calibration, providing a fixed flow of 2 l/min. ➢ For bottles with connector DIN 477-1:1990 No. 14. (External thread, Left-hand thread, M 19 x 1.5)	940288 [old:10.821]
	**Pressure Regulator, Calibration Gas (CHE/FRA)** No longer available ➢ Pressure regulator for exercise gas calibration, providing a fixed flow of 2 liter / min. ➢ For bottles with connector DIN 477-1:1990 No. 6. (External thread, right-hand thread, W 21.80 x 1/14”)	623668 [old:10.823]
	**Accessory Pack for Ergostik** Standard accessory pack containing: ➢ 2 x Exercise mask, (S and XS) ➢ 2 x Headgear, (M and S) ➢ 2 x Exercise mask adapter	852153 [old:10.904]
	**Exercise Mask (Petite, XS, S, M and L)** ➢ Blue silicone rubber exercise mask with anatomically shaped design for leak free comfortable fit. ➢ Five sizes available.	(Petite) 716281 [old: 10.825] (XS) 378734 [old: 10.811] (S) 804885 [old: 10.810] (M) 695262 [old: 10.814] (L) 282025 [old: 10.813]

Component	Description / name	REF
	**Exercise Mask, Pediatric** ➢ Translucent silicone rubber exercise mask for children and adolescents. Two sizes available.	(S) 838093 [old: 10.827] (L) 220830 [old: 10.828]
	**Headgear Small for Exercise Mask** ➢ Soft headgear to fix exercise mask sizes petite and XS.	(XS) 380816 [old: 10.829] (S,M) 144381 [old: 10.812] (L) 477893 [old: 10.834]
	**Headgear Pediatric for Exercise Mask** ➢ Soft headgear to fix exercise mask pediatric sizes S and L.	594009 [old:10.826]
	**Exercise Mask Adapter** ➢ Adapter to fit Ergoflow sensor to exercise mask.	135248 [old:10.815]
	**Silicone Mouthpiece with Saliva Trap** ➢ Silicone rubber bite mouthpiece including saliva trap for use with Ergoflow sensors.	258832 [old:10.819]
	**Pulstik** ➢ USB 2.0 receiver for heart rate from Polar® Transmitter. Runs on Windows based diagnostic software platform BLUE CHERRY®.	493419 [old:40.449]
	**Polar® Soft Strap** ➢ Polar® Soft Strap belt including electrodes.	860695 [old:10.809-01]

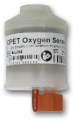
Component	Description / name	REF
	**Polar® H3 Heart Rate Sensor** ➢ Polar® H3 Heart Rate Sensor to measure heart rate and transmit to Pulstik.	187078 [old:10.809]
	**WristOx2® Model 3150 with BLE** ➢ Wireless Bluetooth low energy pulse oximeter providing measurement of oxygen saturation and pulse rate, including strap, Bluetooth USB adapter and batteries.	816016 [old:10.882]
NO IMAGE AVAILABLE	**WristOx2® Model 3150 Activation Key** ➢ Activation Key for the use of the WristOx2® Model 3150 with Bluetooth.	220553 [old:10.532]
	**Soft Finger Sensor** ➢ Soft finger sensor for WristOx2® Model 3150.	318808 [old:10.877]
	**Ear Sensor** ➢ Ear sensor for WristOx2® Model 3150 including 16 to 9 adapter cable.	291945 [old:10.878]
	**Forehead Sensor** ➢ Forehead sensor for WristOx2® Model 3150 including 16 to 9 adapter cable and mounting kit (10 units).	269627 [old:10.879]
	**CO2stik** ➢ USB 2.0 module for continuous correction of ambient CO_2. ➢ Measurement range 0 – 2000 ppm CO_2. ➢ Runs on Windows based diagnostic software platform BLUE CHERRY®.	197357 [old:40.448]

Component	Description / name	REF
NO IMAGE AVAILABLE	**Software option: BGA-Interface** ➢ Imports results from blood gas analyzers via ASTM or HL7.	131393 [old:10.534]
	**Software option: REE Software** ➢ Software option for BLUE CHERRY® to measure resting energy expenditure (Resting Metabolic Rate). ➢ Automatic detection an evaluation of plateau phase data.	526143 [old:10.521]
	**Software option: Training Planer Software** ➢ Software option for BLUE CHERRY® to create individual exercise training plans based on the results of a CPET test.	551941 [old:40.451]
	**Software option: Lactate Software** ➢ Software option for BLUE CHERRY® to interface with existing Ergonizer lactate software to synchronise lactate results.	119616 [old:40.455]
	**Software option: WINLactat Software** ➢ Software option for BLUE CHERRY® to interface with existing Winlactat software to synchronise lactate results.	508249 [old:10.531]
	**Software option: LIPOXmax Software** ➢ Software option for BLUE CHERRY® to calculate LIPOXmax (point of maximal fat consumtion) based on the results of a CPET test.	348061 [old:10.513]

2.2.2 Consumable Items / Auxilary Materials

The following items were tested by the manufacturer for Ergostik. The use of other consumable items as well as auxiliary materials with different properties is deemed improper use.

You will find a list of specialist retail partners as an insert in this IFU or in your medical device book, as well as the most updated version at www.geratherm-respiratory.com/login/

Komponente	Description / name	REF
	**Softclip** ➢ Disposable noseclip for lung function tests. ➢ Made of soft, skin-friendly foam for best wearing comfort ➢ One size	787158 [old:10.200]
	**CPET Oxygen Sensor II** ➢ Oxygen (O_2) measurement cell with fast response time. ➢ Measurement range 0 – 100 % O_2.	318415 [old:40.404]
Disinfectant	**for wipe disinfection**, alcoholic quick-acting ➢ Bacillol Tissues (BODE Chemie GmbH) ➢ Sprayln (Dr. Deppe GmbH)	depend-ing on provider
	for disinfection bath with low chloride concentration ➢ InstruPlus (Dr. Deppe GmbH) ➢ Bomix Plus (BODE Chemie GmbH) ➢ Desinfektion N (ANTISEPTICA Dr. Hans-Joachim Molitor GmbH) ➢ Gigasept Pearls (Schülke & Mayr GmbH) ➢ Milton liquid disinfectant (Milton Pharmaceutical UK Limited)	

3 Safety in Handling

Ergostik has been designed and built in accordance with the state of technology and its recognised safety and technical regulations.

In spite of this, dangers of injury to operators / users, patients and third parties as well as damage to Ergostik or other materials may occur if this is:

- Not used in accordance with the conditions of intended use.
- Not operated in a technically flawless state.
- Operated by untrained or uninstructed personnel.
- Maintained or serviced improperly.

DANGER

In order for Ergostik or the total system to be operated in accordance with its intended use, the safety information and procedures in this IFU must be understood.
Ensure that these are followed!
Otherwise, in the worst case, death or severe injuries are the consequence resulting from the risks described in more detail in the respective chapters!
Therefore:

- **Read this IFU carefully and in its entirety before using the Ergostik. Keep it in close proximity to the medical device for later reference and make it accessible to the user / operator at all times!**
- Also observe the safety information of all other accompanying documents of the total system!
- If you have any questions, ask your authorised specialist retail partner!

3.1 General Safety at Work and Personnel Qualification

⚠ WARNING

Possible danger to life.
Reason: **Not complying with health and safety regulations. Ignoring essential preventive measures.**
Therefore:

- Always comply with general national regulations on accident prevention! Instruct users / operators accordingly!
- Safety and warning information on Ergostik may not be altered or removed! Have missing or not readable information replaced immediately!
- When working with auxiliary materials, always observe the safety information from the respective manufacturer! Wear suitable protective clothing!

Reason: **Electric shock. False diagnosis. Ignoring contraindications. Triggering malfunctions of Ergostik. Unqualified user/ operator can detect sources of failures too late or even cause them.** Therefore:

- Only use officially trained users!
- Users must be familiar with the test methods and their clinical significance!
- All maintenance and servicing work may only be performed by specialised personnel who have been authorised by the manufacturer!

3.2 The Technical State of Ergostik and System Construction

⚠ WARNING

Possible danger to life.
Reason: **Electric shock. Cross-contamination. Misdiagnosis caused by measurement error.**
Therefore:

- Do not overstress Ergostik! Use with care!
- Do not modify or use product Ergostik or total system contrary to the respective manufacturer's specification!
- Only use Ergostik within its expected service life, determined by the manufacturer!
- Under no circumstances use or connect any devices, systems, equipment and other products that are not part of the total system!
- Never obstruct the access to the mains plug or On / Off switch of the equipment cart! Disconnection of the power supply must be easily accessible!
- Only use accessories and consumables which are authorised by the manufacturer as well as authorised replacement components, add-ons and auxiliary materials.
  Check that the components are in a functional and safe condition!
- Ensure that in the patient environment – a distance of 1.5 meters to the patient – there are no accessible electrical parts (interfaces, plugs, etc.) that are not isolated from the mains with an isolation voltage of 4 kV!
- Ensure that the users or third party persons do not touch the patient and any conductive connections or parts of the device that are located outside the patient environment at the same time!

- Ensure that the Ergostik cannot fall down! Otherwise, the functionality must be checked properly before putting it into operation!

Reason: **Electrical shock and / or misdiagnosis due to loss of electrical safety caused by exceeding the recommended maintenance schedule.** Therefore:

- Regularly check the specified maintenance schedules!
- If a maintenance schedule is exceeded, do not continue to use the total system!
- Request maintenance work from your authorised specialist retail partner!
- Only use accessories and consumables which are authorised by the manufacturer as well as authorised replacement components, add-ons and auxiliary materials! Check that the components are in a functional and safe condition!

3.3 Operation / Servicing and Maintenance

DANGER

Danger to life.
Reason: **Electric shock. Explosion. Device damage. Unpredictable movement of metal parts.**
For this: **Comply with the required installation and operating conditions!** Therefore:

- In principle, observe chap. 12 “Technical Specifications"!
- Do not operate Ergostik if there are flammable or explosive gases in the room!
- Do not operate Ergostik near the magnetic field of an MRT system!

WARNING

Possible danger to life.
Reason: **Electrical shock. Cross-contamination or measurement error.** For this: **Ensure that the used components are undamaged and that you are working in a careful way!** Therefore:

- Ensure that the used components are undamaged and that you are working in a careful way!
- Do not use consumable articles with a limited life span after their use-by date has been expired!
- Prior to each use, visually inspect the total system (housing, cables, connectors, tubings, pneumatic connections, etc.) for any damages!
- If there are any damages, do not operate the system! The damaged parts must be replaced or repaired properly!
- Calibrate Ergostik at the intervals stated!

Reason: **Disregard of a contraindication. Misdiagnosis due to measurement errors.** For this**: Observe general medical principles!** Therefore:

- Inform yourself and observe the respective contraindications before each test!
- When carrying out tests, observe the content of the applicable guidelines and recommendations (e.g. ATS / ERS Guidelines)!
- Do not use single use products more than once!

Reason: **Side-effects (i.e. cardiac arrythmia) triggered by exercise.** Therefore:

- Perform exercise tests only in presence of a physician!
- Ensure availability of resuscitation equipment (defibrillator, medications) and trained emergency personnel!
- Monitor cardiac function with appropriate methods (e.g. ECG) during exercise test!

3.4 Electromagnetic Compatibility (EMC)

⚠ WARNING

Possible danger to life.
Reason: **Misdiagnosis due to measurement error caused by a system failure due to uncontrollable electromagnetic fields of inadmissible transmitting devices.** Therefore:

- While using Ergostik, do not use any transmitting devices (e.g. mobile phones, portable phones, power lines …) that exceed the immunity levels as specified in the EMC guidelines!
- Ask your authorised specialist retail partner!

- No stacking of devices on top of each other and no close arrangement. Observe the installation and operating conditions from the manufacturer!
- Check the correct function of the Ergostik!

3.5 Cleaning and Disinfection

WARNING

Possible danger to life.
Reason: **Coss-contamination.** For this: **Observe general medical principles!** Therefore:

- Clean and disinfect Ergostik and its reusable components as instructed by the manufacturer at regular intervals as specified!

Possible severe physical injury.
Reason: **Contamination with transferable germs during improper disposal.** Therefore:

- Dispose single use items (disposable flow sensors, mouthpieces and noseclips) after each use. For this observe the applicable regulatory requirements for biologically hazardous materials!
- Observe regulations on wearing personal protective equipment (PPE)!

CAUTION

Possible physical injury.
Reason: **Misinterpretation of obvious measuring errors (drift) caused by liquid in the tubes.** Therefore:

- Clean tubes only externally!
- Replace dirty tubes!


Achtung

Ergostik could be damaged.
Reason: Penetrating liquids into electronic components.
Therefore:

- Disconnect the Ergostik from the power supply before cleaning and disinfecting!
- (When switching off via the On / Off switch of the equipment cart), shut down the PC completely before doing so!
- Wipe off remaining moisture with a dry cloth!

Reason: Damaged connections. Therefore:

- To disconnect electrical connections, always pull the plug and never the cable!

4 Structure and General Function of Ergostik

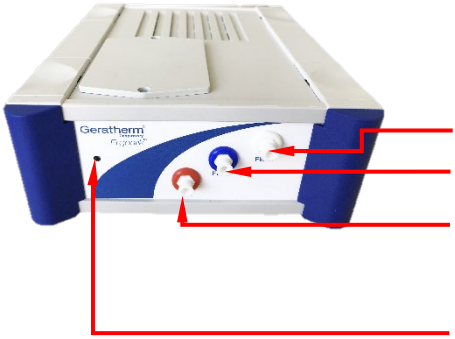
4.1 Hardware

4.1.1 Overview

[1] Ergostik
[2] Medical power supply unit (see also chap. 4.1.3)
[3] Exercise tube set
[4] Ergoflow flow sensor (see also chap. 7.4)
[5] Ambistik
[6] Type label on the bottom of the case (see also chap. 14)
[7] Type label on the bottom of the Ambistik (see also chap. 14)

4.1.2 Connections/ Interfaces of the Ergostik

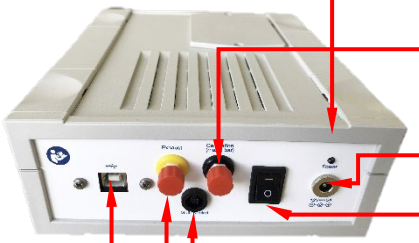
4.1.2.1 Ergostik Device and Connections



Device front view

Flow - Connection
Flow + Connection
Gas-Connection
LED
to show the power supply

Device rear view



Power-LED
Calibration gas connection
12 V DC Power supply unit connection
On-/ Off switch
Multisocket for connecting accessories
Gas outlet
USB-Connection

4.1.2.2 Sensors


Attention

Ergostik could be damaged
Reason: **Sensors are precise and high-resolution components.**
For this: **Ensure the respective functions are preserved!**
Therefore:

- Exactly follow instructions for cleaning, disinfection and calibration!

You will find a detailed description in:

- Chap. 9 "Cleaning and Disinfection"
- The separate IFU Volume Calibration

Flow Sensor

The heart of the Ergostik for precise flow measurement is the Ergoflow flow sensor. It must be calibrated after every cleaning and before the first examination of a day.

As the flow sensor ensures the precise flow measurements, the cleaning and calibration requirements must absolutely be adhered to, regardless of the version selected.

4.1.2.3 Pressure Reducer

For safe use, a suitable pressure reducer for the calibration gas cylinder is required. Please note the following:

Attention

Ergostik could be damaged
Reason: **Working pressure too high.** Therefore:

- Only use a pressure reducer that meets the specifications defined by the manufacturer and provides an outlet pressure of maximum 5 bar!

The manufacturer has approved a suitable pressure reducer as an optional extension. You can get it from your authorised specialist retail partner.

- See also chap. 2.2.1 "Original Spare Parts / Accessories / optional Expansions".

4.1.3 System Construction and Electrical Safety

The following instructions are intended for safe handling of the entire system, taking into account the electrical safety concept of the Ergostik.

The system may be set up only by an authorised specialist retail partner.

It is essential to note: Anyone who combines additional devices or medical devices or unauthorised or non-original components / spare parts / consumables with existing medical, electrical equipment or systems, and this combination is used by third parties or this combination is placed on the market, will legally become a producer of a system or a procedure pack. In any case the assembler of a system is therefore responsible for compliance with the requirements placed on the system by the relevant, harmonised standards and the additional national and international standards and guidelines in the currently valid versions!

You will find a detailed description of the correct system formation in:

- The technical manual "Formation of Systems".

Irrespective of this, please note the following:

⚠ WARNING

Possible danger to life.
Reason: **Electric shock due to lack of galvanic separation with composition of non-approved components.** Therefore:

- Do not modify or use Ergostik or total system contrary to the respective manufacturer's specification!

Reason: **Electrical shock and/or misdiagnosis due to loss of electrical safety caused by exceeding the recommended maintenance schedule.** Therefore:

- Regularly check the specified maintenance schedules!
- If a maintenance schedule is exceeded, do not continue to use the total system!
  Request maintenance work from your authorised specialist retail partner!

Reason: **Misdiagnosis caused by measurement error**.
Therefore:

- Do not connect any additional USB devices! (except mouse, keyboard and printer)
- Do not install any other software!
  Ask your authorised specialist retail partner! which devices are approved by the manufacturer!


Attention

Ergostik could be damaged.
Reason: **Electrostatic discharges.** Therefore:

- Preferably no floor made of synthetic material!
- Otherwise a relative air humidity of at least 30 % is required!

4.1.3.1 Data Connection

The hardware connection between the device and computer is established via an integrated USB interface and USB cable. This is considered to be a spare part approved by the manufacturer and can be obtained from an authorised specialist retail partner.

- See also chap. 2.2.1 "Original Spare Parts / Accessories / optional Expansions"

All measurement results and graphical data can be displayed on the screen as well as printed out via the Windows printer interface. Any printer compatible with Windows can be used for this.

4.1.3.2 Equipment Cart with Isolating Transformer

The cart, approved by the manufacturer, meets the requirements of the IEC 60601 series of standards, so its use is recommended.
You will find more detailed information in:

- Chap. 2.2.1 "Original Spare Parts / Accessories / optional Expansions"
- Respectively consult with your authorised specialist retail partner.

4.1.3.3 Power Supply

The Power Supply is provided by an external desktop Power Supply Unit. Only this is considered a spare part approved by the manufacturer and can be obtained from an authorised specialist retail partner.

- See also chap. 2.2.1.1 "Original Spare Parts / Accessories"

4.2 Technical Protection Measures

Ergostik has been designed and built in accordance with the recognised state of technology and the requirements of the applicable, safety-relevant regulations.

The technical safety condition is checked by the authorised specialist retail partner of the manufacturers within the framework of technical monitoring
(see also chap. 3.3 “Operation / Servicing and Maintenance”)

4.3 Software

The measurement device (Ergostik) is supplied with BLUE CHERRY® software. This serves to manage patient and examination data as well as carry out, depict, process and record measurements with the devices of the manufacturer.

The communication between the BLUE CHERRY® software and a practice computer system or hospital information system is supported by standardised software interfaces (e.g. HL7, GDT). Paid software options are necessary for this, if applicable.

A modular and flexible hardware and software concept makes it possible to combine this with additional measurement options and consequently allows the overall system to be configured separately for individual customers.

For the identification of the current firmware version, this can be read by the BLUE CHERRY® device management system.

For further information see the separate IFU of BLUE CHERRY® – information on the configuration and use of the software BLUE CHERRY®.

5 Transport, Storage and Assembly

5.1 Transport to the Location of Use

The Ergostik is transported secured against damages, in a carton.

The packaging must be kept by the user / operator in case the device must be returned to the authorised distributor or manufacturer.

For further information see:

- Chap. 11 “Decommissioning / Disposal”
- Chap. 15 “Warranty and Service“

The specialist retail partner authorised by the manufacturer are responsible for delivering the Ergostik to the operator and for unpacking and transporting it to the actual installation location.

5.2 Storage

Requirements regarding space requirements, media connections and operating conditions can be found in chap. 12 "Technical Specifications".

The responsible organisation of the Ergostik is solely in charge of compliance with these requirements.

For storage and transport conditions see chap. 12 "Technical Specifications".

5.3 Assembly

Installation or assembly for the first commissioning of the Ergostik may only carried out by qualified personnel of the manufacturer's specialist retail partners.

⚠ WARNING

Possible danger to life.
Reason: **Electric shock. Misdiagnosis caused by measurement error.** Therefore:

- Prevent improper assembly / installation!
- Ergostik should only be assembled and installed by officially trained personnel authorised by the manufacturer!

For further information see:

- Chap. 4.1.3 “System Construction and Electrical Safety”

Information on assembly work in connection with the Recommissioning in:

- Chap. 6.2 "Recommissioning after Servicing / Cleaning Work".

6 Operation

6.1 Initial Operating

The first commissioning of the Ergostik and its recommissioning after maintenance work in accordance with the operator's obligations (see chap. 8 "Servicing / Maintenance"), which is carried out by qualified personnel of the specialist retail partner, is also only carried out by these qualified personnel.

Ergostik is only completely ready to function after calibration and once the initial operation is complete.

6.2 Recommissioning after Servicing / Cleaning Work

The responsible organisation is responsible for returning the device to operation after servicing / cleaning work for which the operator / user is authorised.

Servicing work here also includes the necessary checks which are necessary if Ergostik should fall down.

 Attention	**Ergostik could be damaged.** Reason: **careless operation.** Therefore: • Assure that all cables and tubes are connected carefully! • Generally, do not expose cables, tubes and their connections to mechanical stress such as tension, pressure, bending or similar!

	**Possible danger to life** Reason: **Electric shock.** Therefore: • Never obstruct the access to the mains plug or On / Off switch of the equipment cart! Disconnection of the power supply must be easily accessible!

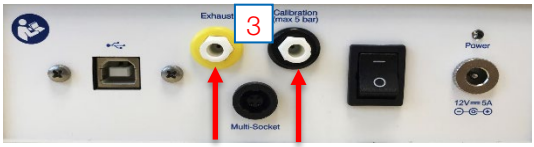
Before the Ergostik can be used to perform measurements again, all components must be properly reconnected, the USB connection to the computer must be established, and the Ergostik must be connected to the power supply and calibrated. Calibration also fulfils the regulatory requirements of MPBetreibV §7 for functional testing after maintenance work.

Please proceed as described in the respective chapters.

6.2.1 Assembly Calibration Tube

⚠ CAUTION	**Possible physical injury.** Reason: **Measurement error due to leakage caused by incorrect assembly of components.** Therefore: • Carefully observe the assembly instructions!

Attention	**Functional disorders possible.** Reason: **Components and e.g. plug connections can be damaged.** Therefore: • All connections must be made carefully and without too much force!



1. **Remove the red protective caps from the calibration gas connection [1] and gas exhaust [2].**
   For this:

   Unscrew the protective caps counterclockwise so that the white marked connections **[3]** are accessible.

2. **Connect the calibration tube to the calibration gas connection.**
   For this:

   Turn calibration tube **[4]** clockwise.

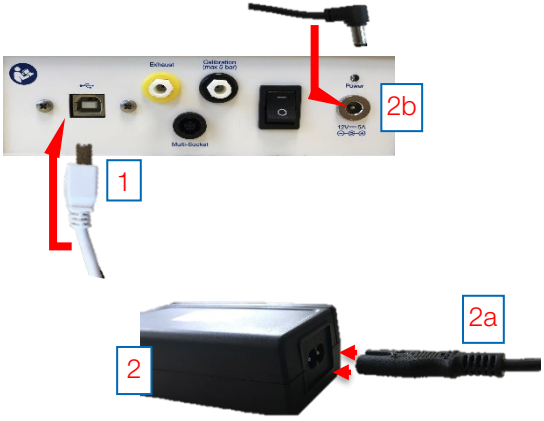
3. **Connect the minifilter to the gas exhaust**
   For this:

   Turn the minifilter **[5]** clockwise.

6.2.2 Power Supply and PC-Connection

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock due to lack of galvanic separation with composition of non-approved components.** Therefore: Only use the • Power Supply • USB-Connection Cable supplied by the manufacturer as spare parts, which are always part of the medical device. (See chap. 2.2.1.1 “Original Spare Parts / Accessories“)

Connect the Ergostik in order to make it ready for operation:



1. **USB- connection cable [1]**
   to the USB socket of the Ergostik.

2. **Power supply unit [2]**
   with
   power cord **[2a]** and the power supply connection on the Ergostik **[2b]**
   Insert the power plug into the socket

7 Operating Instructions

7.1 Checking for Worn Parts

The Ergostik should be checked for defective wearing parts each day before beginning treatments.
You can get a description in:

- Chap. 8 “Servicing / Maintenance”

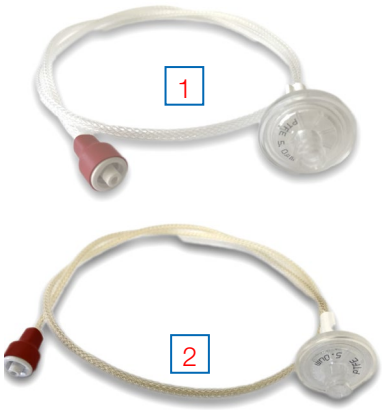
And:

⚠ WARNING

Possible danger to life.
Reason: **Misdiagnosis caused by measurement error due to incorrect components or improper use.**
Therefore:

- Replace the flow sensor and the mouthpiece in case of a functional error!
- Always follow instructions (see chap. 8 "Servicing / Maintenance" and chap. 9 "Cleaning and Disinfection")!

7.1.1 Minifilter / Permapure Check



The permapure drying tube and minifilter must be checked regularly for discoloration.

Please note that the permapure tube and minifilter are transparent as shown in Fig. **[1]** and are not severely discoloured as shown in Fig. **[2].**

If the permapure tube turns brown during the course of use, it should be replaced together with the minifilter.

7.2 Establishing Operational Readiness

To make the Ergostik ready for operation, please read the instructions:

- Chap. 7.5ff "Calibrating Ergostik“

7.3 Switching Ergostik On / Off

⚠ CAUTION

Possible physical injury.
Reason: **misinterpretation of obvious measurement errors (drift).** Therefore:

- Let the Ergostik warm up for 15 minutes! Measurements may only be performed after this time!

The Ergostik can be switched off by disconnecting the power supply. When using a cart, this is done via the On / Off switch on the cart. Otherwise, the On / Off switch on the back of the Ergostik must be activated.

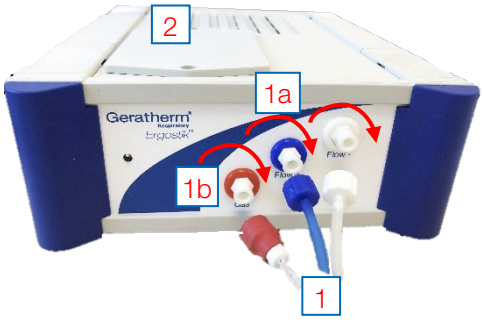
To extend the life of the gas sensors, the Ergostik should be switched off if there are long intervals between measurements. After switching on the Ergostik needs a warm-up time of 15 minutes. Only after this time is the Ergostik ready for operation.

Detailed information on how to establish operational readiness you will find here:

- In this IFU – chap. 7.2 "Establishing Operational Readiness".

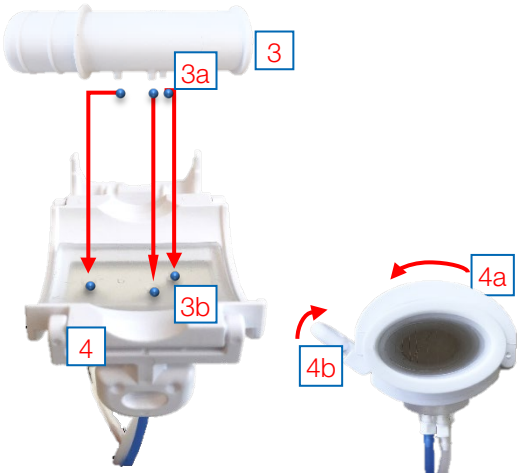
If the calibration as described in chap. 7.5 "Calibrating Ergostik" has not been carried out already, this must be done later, otherwise no functional readiness is possible.

7.4 Inserting the Flow Sensor



1. **Connect the exercise tube set [1] with the Ergostik [2]**
   For this:

   Screw the flow- **[1a]** and gas tubes **[1b]** clockwise to the color-coded connections on the front of the Ergostik.



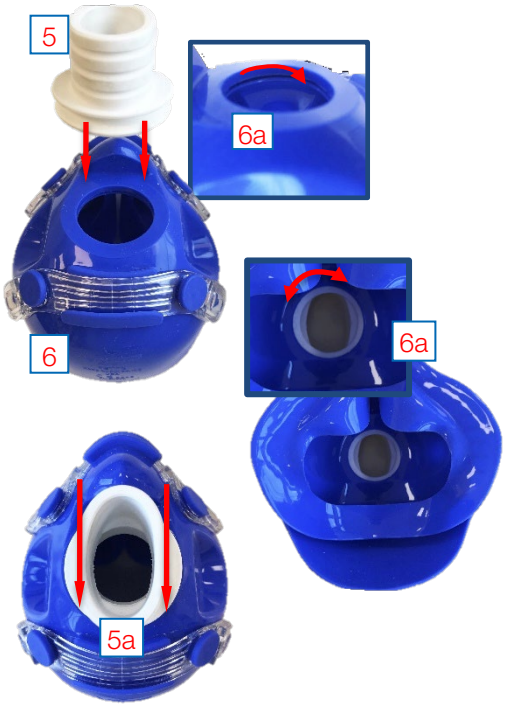
2. **Insert the Ergoflow flow sensor [3].**
   For this:

   Press the side with the connection pins **[3a]** vertically onto the Ergoclip adapter **[4]**, which is located on the tube set, until the connection pins and the openings provided for them are connected **[3b].**

3. **Close and lock the closing cap [4a].**
   For this:

   Close the cover cap and push the closure **[4b]** upwards until it engages.

7.4.1 Assembly Face Mask

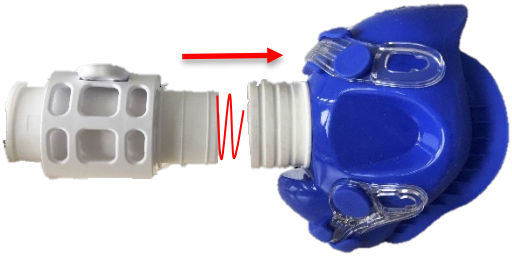


1. a) Assemble the mask adapter [5] to the face mask [6].
   For this:

   Press the adapter through the round opening of the silicone mask so that the lower ring of the adapter is inserted into the incision [6a].

   b) Position the adapter.
   For this:

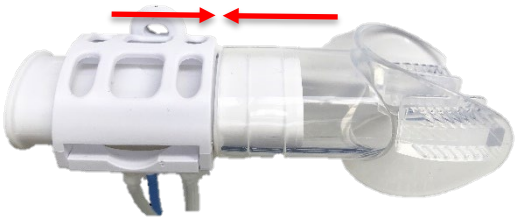
   Position the oval opening [5a] of the adapter vertically to the face mask.



2. Mount the flow sensor in the Ergoclip adapter on the face mask.
   For this:

   Press the flow sensor with the patient close side into the receptacle provided on the adapter.

7.4.2 Assembly Silicone Mouthpiece



1. **Assemble the flow sensor in the Ergoclip adapter to the silicone mouthpiece.**
   For this:

   Press the flow sensor with the patient close side into the receptacle provided on the adapter.

7.5 Calibrating Ergostik

There are various processes to be carried out for Ergostik in order to calibrate or validate the volume and gas measurement.

The required intervals can be found in the tables below.

For details on individual calibrations, please read:

- The separate IFU: Calibration

Interval	Calibration
Once per day	Gas calibration
Once per day, and after changing the flow sensor	Volume calibration
Once per week	Flow linearity test
After Maintenance / Cleaning	Volume calibration
If required / conspicuous measured values	Plausibility check: An employee performs spiroergometry and compares it with previous results.

7.6 Using Ergostik / Performing Measurements

Descriptions of the individual examinations can be found in the separate IFU:

- CPET

And for general use of the software:

- BLUE CHERRY®

⚠ WARNING

Possible danger to life.
Reason: **Disregard of a contraindication. Misdiagnosis due to measurement errors.** For this: **Observe general medical principles!** Therefore:

- Inform yourself and observe the respective contraindications before each test!
- When carrying out tests, observe the content of the applicable guidelines and recommendations (e.g. ATS/ERS Guidelines)!

Reason: **Misdiagnosis due to measurement error caused by a system failure due to uncontrollable electromagnetic fields of inadmissible transmitting devices.** Therefore:

- While using Ergostik, do not use any transmitting devices (e.g. mobile phones, portable phones, power lines …) that exceed the immunity levels as specified in the EMC guidelines!
- Ask your authorised specialist retail partner!

Reason**: Electrical shock.** Therefore:

- Ensure that the users or third party persons do not touch the patient and any conductive connections or parts of the device that are located outside the patient environment at the same time!

Reason: **Cross-contamination.** For this: **Observe the general medical principles!** Therefore:

- Do not use single use products more than once!

Reason: **Side-effects (i.e. cardiac arrythmia) triggered by exercise.** Therefore:

- Perform exercise tests only in presence of a physician!
- Ensure availability of resuscitation equipment (defibrillator, medications) and trained emergency personnel!
- Monitor cardiac function with appropriate methods (e.g. ECG) during exercise test!

Attention

Ergostik could be damaged.
Reason: **Penetrating liquid. Uncleanliness. External exposure.** Therefore:

- Do not use any liquids near Ergostik!
- Do not expose Ergostik or the entire system to dust or other contamination!
- Do not drop any objects on Ergostik!
- Do not lay any objects on it!
- Never push foreign objects into the housing!

Reason: **Condensation**. Therefore:

- Do not expose the device to excessive temperature fluctuations during operation!

7.7 Exchange of Disposable Products / Disinfection

7.7.1 Noseclip

⚠ WARNING	**Possible danger to life.** Reason: **Cross-contamination.** For this**: Observe the general medical principles!** Therefore: • Do not use single use products more than once! • Dispose of noseclip after each use!

The noseclip must be disposed after each examination or patient.

For further weekly cleaning and disinfection tasks, please see:
- Chap. 9 “Cleaning and Disinfection”

Information about disposal of the disposable products can be found in:
- Chap. 11.3 "Disposal"

7.7.2 Ergoflow / Mask / Mouthpiece

All parts which have come into contact with the patient or patient breathing during the examination must be disinfection.

For further weekly cleaning and disinfection tasks, please see:
- Chap. 9 “Cleaning and Disinfection”

Information about disposal of the disposable products can be found in:
- Chap. 11.3 "Disposal"

8 Servicing / Maintenance

8.1 Duties of the Responsible Organisation

Responsible organisations of medical devices are obligated, in accordance with the corresponding, applicable regulations, to preserve the properties of this medical device assured by the manufacturer over its whole service life. This also includes carrying out regular and proper servicing as well as safety checks at intervals recommended by the manufacturer carried out by specialist personnel who have been authorised by the manufacturer for the respective tasks.

The expected service life of Ergostik is 8 years.

In its development, a great deal of value was placed on making the servicing of all device components as simple as possible. Only a little work is necessary to guarantee a fault-free operation of the device.

However, to maintain a high quality of measurement results and the safe operation, the manufacturer recommends having the device safety and measurement precision checked by an authorised specialist retail partner every 24 months.

These checks include:

- Visual check
- Electrical measurement
- Functional Check

⚠ WARNING	**Possible danger to life.** Reason: **Electric shock and/or misdiagnosis due to loss of electrical safety caused by exceeding the recommended maintenance schedule.** Therefore: • Regularly check the specified maintenance schedule! • If a maintenance schedule is exceeded, do not continue to use the total system! Request maintenance work from your authorised specialist retail partner!

Attention	Independent of this, the user / operator must carry out regular checks during day-to-day operation, see also the following chap. 8 “Servicing / Maintenance by the User”!

8.2 Servicing / Maintenance by the User / Operator

In order to ensure a flawless operation of Ergostik over its whole service life, regular servicing and repairs, if applicable, are required.

Intervall	Servicing work
Before each examination	Checking the cable and tube connections
Once per day	Visual checks of the device and its components for damage and replacing them if necessary (see chap. 8.2.1 “Checking / Exchanging of Tubes and Cables”)
After about 50 to 100 examinations	Replacing the permapure tube and filter
After 12 months	Replacing the exercise tube set
After 12 months	Replacing the CPET Oxygen Sensor II

⚠ WARNING

Possible danger to life.
Reason: **Electric shock. Misdiagnosis caused by measurement error.** For this: **Ensure that the used components are undamaged and that you are working in a careful way!** Therefore:

- Prior to each use, visually inspect the total system (housing, connectors, etc.) for any damages!
- If there are any damages, do not operate the system. The damaged parts must be replaced or repaired properly!

Reason: **Electric shock. Triggering malfunctions of Ergostik. Unqualified user / operator can detect sources of failures too late or even cause them.** Therefore:

- All maintenance and servicing work may only be performed by specialised personnel who have been authorised by the manufacturer!

8.2.1 Checking / Exchanging of Tubes and Cables

All parts of Ergostik should be checked for visible mechanical damage (cracks, tears) each day. If damage is ascertained, the corresponding component must be replaced.

For replacing components see:

- Chap. 4.1.3 “System Construction and Electrical Safety“
- Chap. 6.2 “Recommissioning after Servicing / Cleaning Work“

9 Cleaning and Disinfection

The devices of the manufacturer were designed in such a way that minimal effort is required for cleaning and disinfection. This is why just a few tasks are necessary to keep Ergostik functional and clean.
Cleaning and disinfection may cause discolouration of the components, but without impairing their function.
The following intervals apply:

Component	Interval	Method
Noseclip	After each patient	Dispose of!
Silicone mouthpiece	After each patient	Cleaning and disinfection bath
Face mask	After each patient	Cleaning and disinfection bath
Mask adapter	After each patient	Cleaning and disinfection bath
Network mask	After each patient	Cleaning and disinfection bath
Reusable flow sensor, Ergoflow	After each patient	Cleaning and disinfection bath
Ergostik	Weekly	Wipe / surface disinfection
Ergoclip	After each patient	Wipe / surface disinfection
All other touchable parts	Weekly	Wipe disinfection

⚠ CAUTION

Possible physical injury.
Reason: **misinterpretation of obvious measuring errors (drift) caused by liquid in the tubes.** Therefore:

- Clean tubes only externally!
- Replace dirty tubes!


Attention

Ergostik could be damaged.
Reason: **Penetrating liquid into electrical components.**
Therefore:

- Disconnect the Ergostik from the power supply before cleaning and disinfecting!
- (When switching off via the On / Off switch of the equipment cart), shut down the PC completely before doing so!
- Wipe off remaining moisture with a dry cloth!

Ergostik could fail.
Reason: **Damaged connections**. Therefore:

- To disconnect electrical connections, always pull the plug and never the cable!

9.1 Single Use

For instructions on handling noseclips, read:

- Chap. 7.7 “Exchange of Disposable Products / Disinfection”

9.2 Disinfection

All parts of the Ergostik can be cleaned of dirt with a soft cloth using a cleaning solution / weak soapy water.

All parts of Ergostik which come into contact, or could come into contact, with the patient must be treated with a surface disinfection. Otherwise, these can be wiped with a soft cloth using a weak soap solution.

When using a disinfectant that has not been tested and approved by the manufacturer, the following steps must be observed:

- Preferably use agents that correspond in composition to the approved agents. The composition is available on data sheets, which we can provide on request.
- Check bactericidal and virucidal effect suitable for the intended use.
- Use only disinfectants listed in public databases (e.g. RKI)
- Check data sheet for material compatibility with plastics (especially polyoxymethylene, polystyrene, acrylonitrile butadiene styrene, Makrolon®) as well as metal
- First test the disinfectant for material compatibility in an inconspicuous place.
- During the regular visual inspection for damage, also pay attention to material changes (discoloration, cracks, embrittlement...)
- Observe long-term trend of calibrations for changes in measuring function

The manufacturer accepts no liability for any resulting equipment damage or any consequential damage caused by the use of disinfectants that have not been tested and approved by the manufacturer.

Attention

Ergostik could be damaged.
Reason: Improper treated components. Therefore:

- For cleaning and disinfection only use those active substances that are approved by the manufacturer! (See chap. 2.2.2 "Consumable Items / Auxilary Materials")!
- Follow the instructions on the concentration and dwell time stated by the cleanser and disinfectant manufacturer!
- Do not place Ergostik in the cleaning and disinfection solutions! The device contains electrical components that will be damaged by doing so!

For the selection of suitable disinfectants please note:

- Chap. 2.2.2 "Consumable Items / Auxilary Materials".

9.2.1 Ergostik

All parts of the Ergostik which come or could come into contact with the patient must be treated with surface disinfection.

9.2.2 Flow Sensor- / Ergoclip Removal

1. **Remove Ergoflow.**
   For this:

   Proceed in reverse order as described in chap. 7.4 “Inserting the Flow Sensor“.

2. **Perform wipe disinfection.**
   For this:

   Wipe all accessible surfaces with a wet disinfecting cloth.

Attention

Ergostik could be damaged
Reason: **destruction of the orifice.** Therefore:

- Do not clean the interior of the sensor, mechanical or with hard water jet!
- Do not use any disinfectants which contain high chloride concentrations!

Reason: **Improper treated components**. Therefore:

- Observe the maximum permissible temperature of 75 °C for cleaning and disinfection!
- Do not dry with heat!

Possible impairment of the measuring function.
Reason: **Moisture in the connection port.** Therefore:

- Ensure that there is no moisture in the connection piece before recommissioning!

1. Remove the flow sensor.
   (In reverse order as in chap. 7.4. "Inserting the Flow Sensor" described).
2. Wipe off visible contamination with a soft cloth.
3. Put the sensor in disinfectant fluid.
4. Wash the sensor in distilled water thoroughly so that no residual dirt and disinfectants remain.
5. Air-dry sensor until no moisture is visible.

9.2.3 Removing the Silicone Mask / Adapter

1. Remove the adapter.
   (In reserve order as described in chap. 7.4.1 “Assembly Face Mask“)
2. Wipe off visible contamination. with a soft cloth.
3. Insert the adapter and silicone mask into a disinfectant solution.
4. Wash the adapter and silicone mask thoroughly in distilled water so that no residues of contamination and disinfectants remain
5. Air-dry adapter and silicone mask until no moisture is visible.

10 Fault Indication and Repair

Simple errors which occur when using Ergostik can be recognised quickly and rectified using the following table. If you cannot find the error in the table or the problem cannot be rectified using the method described, please contact your specialist retail partner.

You will reach your authorised specialist retail partner via contact form on the manufacturer's website www.geratherm-respiratory.com/login/

DANGER

Danger to life.
Reason: **Unauthorised work carried out by the user to troubleshoot and rectify an error.** Therefore:

- Users may only carry out work which is described and permitted by the manufacturer!

In case of not complying with this restriction, the responsible organisation alone is liable for any resulting injuries to persons and/or damages to Ergostik!

Error	Rectification
Device is not recognised	Check power supply (power supply unit and power cable)
	Check power switch on the Ergostik
	Check USB connection between PC and Ergostik
	Switch the Ergostik off and on with the power switch

No flow signal	Check that the Ergoflow is correctly positioned in the Ergoclip
	Check the tube connection between Ergoclip and Ergostik
Drift on flow signal	Check that the Ergoflow is correctly positioned in the Ergoclip
	Check the tube connection between Ergoclip and Ergostik
	Check for moisture in the tube / connection piece of the Ergoflow
	Perform volume calibration
No gas signal	Check that the Ergoflow is correctly positioned in the Ergoclip
	Check the tube connection between Ergoclip and Ergostik
	Check for moisture in the tube / connection piece of the Ergoflow
	Perform gas calibration
Drift on gas signal	Note the warm-up time of the Ergostik (15 minutes)
	Check for moisture in the tube / connection piece of the Ergoflow
	Perform gas calibration
Software error message "Unit warm-up not completed.	Note the warm-up time of the Ergostik (15 minutes)
Software error message "Flow out of measuring range".	Check that the Ergoflow is correctly positioned in the Ergoclip
	Check tube connection between Ergoclip and Ergostik
	Check for moisture in the tube / connection piece of the Ergoflow

Software error message "O_2 out of measuring range“	Check tube connection between Ergoclip and Ergostik
	Check for moisture in the tube / connection piece of the Ergoflow
	Check gas outlet for blockage
	Perform gas calibration
	Check the set type of the O_2 Sensor
Software error message "CO_2 out of measuring range	Check tube connection between Ergoclip and Ergostik
	Check for moisture in the tube / connection piece of the Ergoflow
	Check gas outlet for blockage
	Perform gas calibration
obvious measuring error	Check that the Ergoflow is correctly positioned in the Ergoclip
	Check tube connection between Ergoclip and Ergostik
	Check for moisture in the tube / connection piece of the Ergoflow
	Check the tightness of the Mask / Mouthpiece
	Check last calibration date and recalibrate if necessary (see chap. 7.5)

11 Decommissioning / Disposal

11.1 Expected Service Life

The expected service life of Ergostik has been stated by the manufacturer as 8 years.

This applies provided the operating conditions, the prescribed servicing intervals, taking into account and complying with all safety information such as is described in this IFU as well as other technical standard regulations are adhered to.

11.2 Decommissioning

To decommission the Ergostik, remove any contaminated material from it.

11.3 Disposal

In general, the applicable national laws and regulations stipulated by the local authority should be complied with for disposal.

11.3.1 Transport Packaging

The transport packaging should be reused or sent for material recycling. Before doing so, you should check whether it is possible to reuse the packaging.

11.3.2 Ergostik

Ergostik is an active medical device and is thus subject to the WEEE directive 2012 / 19 / EU and the German law on electrical and electronic devices (ElektroG) for the disposal for old electrical items. Neither Ergostik itself, nor any of its components may be disposed of via household or practice waste.

In order to ensure environmentally friendly disposal, please contact the authorised specialist retail partner where you purchased Ergostik and/or the accessories.

11.3.3 Infectious / Contaminated Single Use Items

All contaminated items such as mouthpieces and noseclips must be disposed of trough the hospital or medical practice waste.

⚠ WARNING	**Possible severe physical injury.** Reason: **Contamination with transferable germs during improper disposal.** Therefore: • Dispose single use items (disposable flow sensors, mouthpieces and noseclips) after each use. For this observe the applicable regulatory requirements for biologically hazardous materials! • Observe regulations on wearing personal protective equipment (PPE)!

12 Technical Specifications

12.1 Technical Data

Medical device:	Class IIa (in accordance with MDD 93 / 42 Council Directive of 14/6/1993 annex IX)
Dimensions:	(L) 210 mm x (W) 175 mm x (H) 75 mm
Weight:	1120 g

Electrical data:	
Protection class:	II
Protection type:	IP20 IEC 529
Applied part:	BF according VDE 0750 (DIN EN 60601-1)
PC interface:	USB 2.0
Power supply:	12 V DC max. 5 A
Power consumption:	< 60 VA

EMC:	Group 1 / Class B
Noise emission:	< 80 dB(A)

Surface temperature:	
Normal operation:	< 41 °C

Flow measurement:	
Flow sensor:	Ergoflow
Measuring principle:	Differential pressure
Measuring range:	±16 l/s
Ventilation measuring range:	0 – 300 l/min
Flow resistance:	< 0.12 kPa/(l/s) < 14 l/s
Dead space:	< 32 ml
Flow resolution:	15 Bit
Sample rate:	125 Hz

Accuracy:	±3 % or 50 ml/s

Volume:

Measuring range:	0 – 20 l
Accuracy:	±3 % or 50 ml

O_2:

Principle:	Electrochemical cell
Range:	1 - 100 %
Accuracy:	± 0.1 vol% (13 % - 21 %) / ± 1 % FS
t10-90:	< 90 ms (after filtering)

CO_2:

Principle:	Infrared spectroscopy
Range:	0 - 13 %
Accuracy:	± 0.1 vol% (2.5 % - 7.5 %)
t10-90:	< 90 ms (after filtering)

Minimum PC system requirements:

Standard:	at least EN 62368-1 / EN 60950 recommended EN 60601
Processor:	X86 / amd64 compatible, 1 GHz or higher
RAM storage:	1 GB or higher
Hard drive storage:	5 GB or higher
Monitor:	XGA (1024 x 768) or higher
PC interface:	USB 2.0 recommended
Operating system:	Windows 8.1 or higher

12.2 Installation and Operating Conditions

The following conditions supplement chap. 2.2 "Intended Use" and must be observed to maintain the properties of the Ergostik guaranteed by the manufacturer and for the safety of the patient and operator.

Storage / Transport:	min.	max.	
Temperature:	-10 °C	+50 °C	
Relative air humidity:	10 %	95 %	non-condensing
Atmospheric pressure:	700 hPa	1100 hPa	

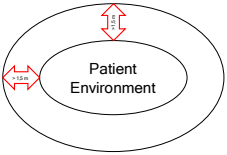
Operation:	min.	max.	
Environmental temperature:	+10 °C	+35 °C	Avoid extreme fluctuations in temperature!
Relative air humidity:	20 %	95 %	non-condensing
	(at least 30 % for synthetic flooring)		
Atmospheric pressure:	700 hPa	1100 hPa	

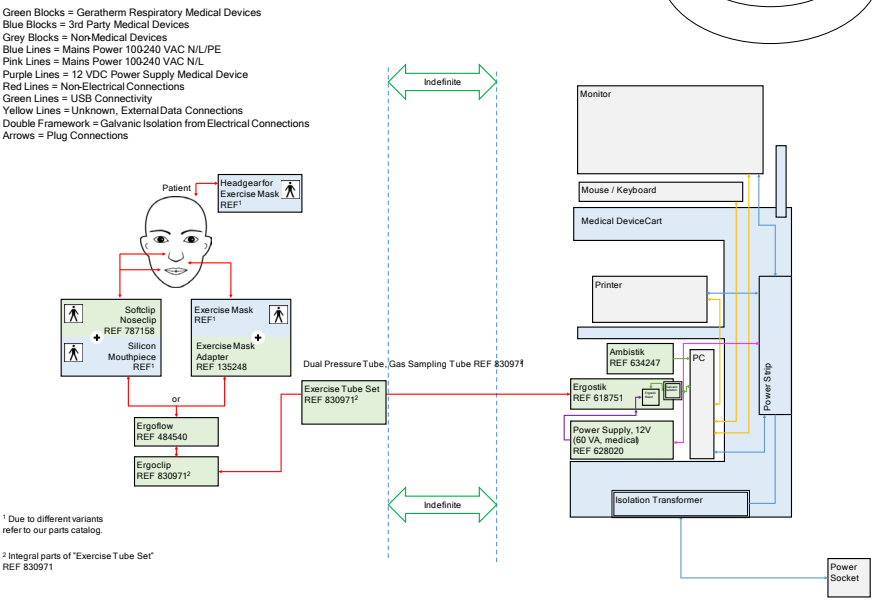
Setup:	mobile
Space requirement: (complete with medical cart)	(L) 900 mm x (W) 900 mm x (H) 1900 mm
Required floor load capacity:	150 kg/m^2
Flooring:	stable; even; conductive
	preferably no synthetic material
Environment / room:	Closed, clinical area
	air-conditioned
	not an explosive or flammable environment!
	not near an MRI!
	well ventilated
Operating Mode:	Continuous operation

12.3 Electrical Safety Concept

12.3.1 Ergostik with Medical Device Cart and Isolation Transformer

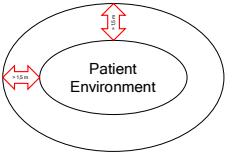
- External Medical Power Supply for Ergostik (Protection Class 2)
- Communication with PC via USB-Interface
- USB/PC Galvanic Isolation in Ergostik
- With Isolation Transformer via Medical Device Cart



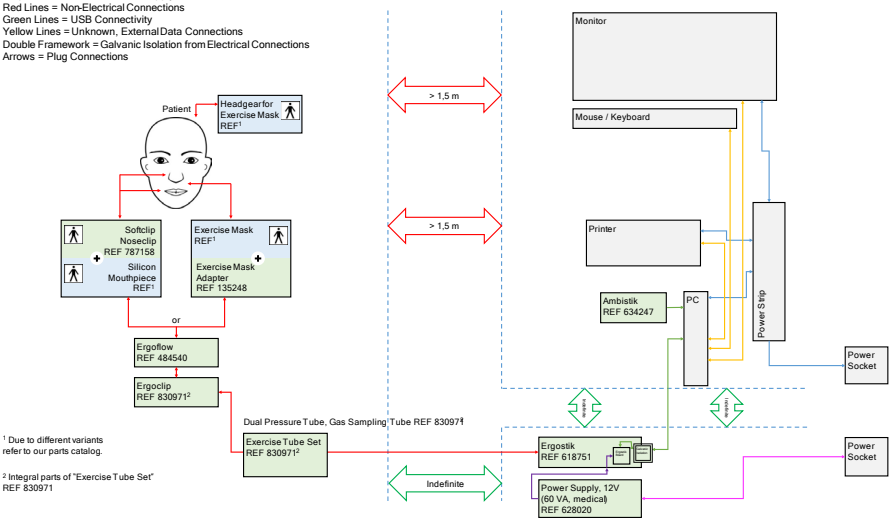


12.3.2 Ergostik without Medical Device Cart and without Isolation Transformer

- External Medical Power Supply for Ergostik (Protection Class 2)
- Communication with PC via USB-Interface
- USB/PC Galvanic Isolation in Ergostik
- Without Medical Device Cart, without Isolation Transformer



Green Blocks = Geratherm Respiratory Medical Devices
Blue Blocks = 3rd Party Medical Devices
Grey Blocks = Non-Medical Devices
Blue Lines = Mains Power 100240 VAC N/L/PE
Pink Lines = Mains Power 100240 VAC N/L
Purple Lines = 12 VDC Power Supply Medical Device
Red Lines = Non-Electrical Connections
Green Lines = USB Connectivity
Yellow Lines = Unknown, External Data Connections
Double Framework = Galvanic Isolation from Electrical Connections
Arrows = Plug Connections



[1] Due to different variants refer to our parts catalog.

[2] Integral parts of "Exercise Tube Set" REF 830971

12.4 Electromagnetic Compatibility / EMC Guidelines

The manufacturer tests his products for emitted interference and interference resistance. Compliance with the relevant standards and directives is certified in the Declaration of Conformity that accompanies this device. The results of the EMC test can be found in the following chapter.

12.4.1 Emitted Interference Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic emissions		
The **Ergostik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Ergostik** should ensure that it is operated in this environment.		
Measurement of electromagnetic emissions	Compliance	Electromagnetic environment – Guideline
RF emissions CISPR 11	Group 1	The **Ergostik** uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and is improbable to interfere with adjacent electronic equipment.
RF emissions CISPR 11	Class B	The **Ergostik** is suitable for use in all establishments, including living areas and those directly connected to the public supply network, which also supplies buildings used for residential purposes.
Emissions of harmonic oscillations according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	Compliance	

12.4.2 Interference Resistance for all ME Systems Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The **Ergostik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Ergostik** should ensure that it is operated in this environment.			
Measurement of interference immunity	IEC 60601 – test level	Compliance level	Electromagnetic environment – Guideline
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical disturbances Bursts according to IEC 61000-4-4	±2 kV for power cables ±1 kV for input and output lines	±2 kV for power cables ±1 kV for input and output lines	The quality of the supply voltage should be appropriate for a typical business- or hospital environment
Surges according to IEC 61000-4-5	±1 kV Voltage outer conductor - outer conductor ±2 kV Voltage outer conductor end	±1 kV Voltage outer conductor - outer conductor ±2 kV Voltage outer conductor end	The quality of the supply voltage should be appropriate for a typical business or hospital environment
Voltage dips, short interruptions and supply voltage fluctuations according to IEC 61000-4-11	0% U_T, ½ Period at 0, 45, 90, 135, 180, 225, 270, 315 Degree	0% U_T, ½ Period at 0, 45, 90, 135, 180, 225, 270, 315 Degree	The quality of the supply voltage should be appropriate for a typical business or hospital environment. If the user of the **Ergostik**-system requires continued operation even during power interruptions, it is recommended that the PFT system be powered from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to the typical values as found in the business and hospital environment.

12.4.3 Interference Resistance for None-Life-Supporting ME Systems Guideline and Manufacturer Declaration

Guidelines and manufacturer's declaration – electromagnetic interference immunity			
The **Ergostik** is determined for operation in an electromagnetic environment as specified below. The user / operator of the **Ergostik** should ensure that it is operated in this environment.			
Measurement of interference immunity	IEC 60601 -level	Compliance level	Electromagnetic enviroment - Guidline
			Portable and mobile RF communication devices should not be used at a shorter distance from the **Ergostik** as the recommended safety distance calculated according to the equation applicable to the transmission frequency.
			Recommended safety distance:
Conducted HF-distrubance variable IEC 61000-4-6	3 V Effective value 150 kHz to 80 MHz	U_1= 3 V	$d = \left[\frac{3.5}{U_1}\right]\sqrt{P}$
	6 V Effective value **ISM-frequency bands:** 6.765 MHz to 6.795 MHz 13.553 MHz to 13.567 MHz 26.957 MHz to 27.283 MHz 40.66 MHz to 40.70 MHz **Amateur Radio frequency bands:** 1.8 MHz to 2.0 MHz 3.5 MHz to 4.0 MHz 5.3 MHz to 5.4 MHz 7 MHz to 3 MHz	U_2= 6 V	$d = \left[\frac{6}{U_2}\right]\sqrt{P}$

	10.1 MHz to 10.15 MHz 14 MHz to 14.2 MHz 18.07 MHz to 18.17 MHz 21.0 MHz to 21.4 MHz 24.89 MHz to 24.99 MHz 28.0 MHz to 29.7 MHz 50 MHz to 54.0 MHz		
Radiated HF-distrubance according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	E_1= 3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ from 80 MHz up to 800 MHz
			$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ from 800 MHz up to 2.7 GHz
	27 V/m, PM 18 Hz, 385 MHz	E_2= 27 V/m PM 18 Hz	$d = \left[\frac{6}{E_2}\right]\sqrt{P}$
	28 V/m FM± 5 kHz Hub 1 kHz Sinus, 450 MHz	E_3= 28 V/m FM± 5 kHz Hub 1 kHz Sinus	$d = \left[\frac{6}{E_3}\right]\sqrt{P}$
	9 V/m PM 217 Hz, 710 MHz, 745 MHz, 780 MHz	E_4= 9 V/m PM 217 Hz	$d = \left[\frac{6}{E_4}\right]\sqrt{P}$
	28 V/m PM 18 Hz, 810 MHz, 870 MHz, 930 MHz	E_3= 28 V/m PM 18 Hz	$d = \left[\frac{6}{E_3}\right]\sqrt{P}$
	28 V/m PM 217 Hz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	E_3= 28 V/m PM 217 Hz	$d = \left[\frac{6}{E_3}\right]\sqrt{P}$

	9 V/m PM 217 Hz, 5240 MHz, 5500 MHz, 5785 MHz	E_4= 9 V/m PM 217 Hz	$d = \left[\frac{6}{E_4}\right]\sqrt{P}$
			P is the maximum rated power of the transmitter in watts (W) according to the manufacturer's specifications and *d* is the recommended safety distance in meters (m) Field strengths from fixed RF transmitters should be less than the compliance level at all frequencies according to on-site investigations. Interference may occur in the environment of equipment marked with the following symbol: 
Note 1: The higher frequency range shall be used at 80 MHz and 800 MHz. Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is influenced by absorptions and reflections from buildings, objects and people.			
a) The field strengths of stationary transmitters, such as base stations and mobile land-based radios, amateur radio stations, AM and FM radio and television transmitters, can theoretically not be predicted exactly. In order to determine the electromagnetic environment with regard to the stationary transmitters, a study of the electromagnetic phenomena of the site should be considered. If the measured field strength at the site where the **Ergostik** is used exceeds the abovementioned compliance levels, the **Ergostik** should be observed to demonstrate its intended function. If unusual performance characteristics are observed, additional measures may be required, such as a change in orientation or in location of the **Ergostik**. b) Over the frequency range from 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.			

12.4.4 Recommended Safety Distances for Non-Life-Supporting ME Systems

Recommended safety distance between portable and mobile RF communication devices and the Ergostik

The **Ergostik** is determined for operation in an electromagnetic environment in which the RF disturbances are controlled. The user / operator of the **Ergostik** may help to avoid electromagnetic interference by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **Ergostik**, depending on the emitted power of the communication device as indicated below:

Power rating of the transmitter [W]	Safety distance, depending on the transmitter frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters whose maximum power rating is not given in the table above, the recommended safety distance *d* in meters (m) can be determined using the equations given with each column, where *P* is the maximum power rating of the transmitter in watts (W) as specified by the manufacturer.

Note 1: The higher frequency range shall be used at 80 MHz and 800 MHz.
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic parameters is influenced by absorptions and reflections from buildings, objects and people.

13 Safety of Product and Material

The manufacturer develops, produces and tests its products according to the essential requirements of MDD 93 / 42 EEC and the safety standards of DIN EN 60601-1.

All materials which are used are carefully selected and correspond to the biocompatibility requirements (in accordance with ISO 10993-1 ff) and those of the RoHS directive 2011/65/EU (RoHS II). All materials in contact with the patient were evaluated and tested according to DIN EN ISO 10993-1:2017-04 "Biological evaluation of medical devices" (biocompatibility).

Ergostik is a class IIa active medical device. Conformity with the underlying standards and directives is certified in the declaration of conformity which is included in the documentation accompanying the device.

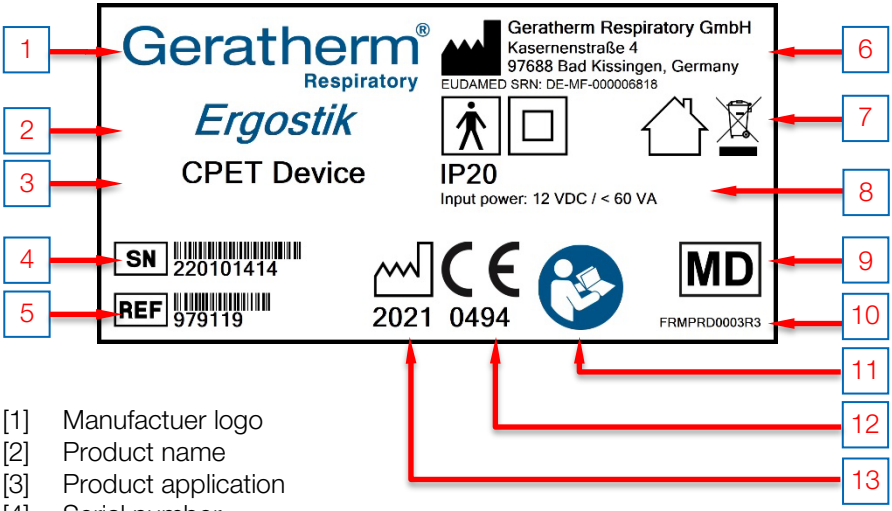
14 Product Labeling / Type Label

The type label can be found on the bottom of the Ergostik.

- See chap. 4.1.1 “Overview” point [6].

For more information about the symbols:

- See chap. 1.3 “Symbols”.



[1] Manufactuer logo
[2] Product name
[3] Product application
[4] Serial number
[5] Catalog number
[6] Manufacturer details
[7] For symbol descriptions see chap 1.3 "Symbols".
[8] Input power
[9] Medical Device
[10] Type label revision indication
[11] Follow the IFU
[12] Conformity mark in accordance with the Medical Device Directive 93 / 42 / EEC with identification of the involved notified body
[13] Date of manufacture

Safety symbols have been applied to the Ergostik type label. It may not be changed or removed. If information should become unreadable, the type label should be replaced immediately. Contact the manufacturer to do this.

15 Warranty and Service

15.1 General Conditions

The manufacturer guarantees that the products you have purchased fulfill the listed technical data and that the medical devices are free from technical material and production defects. This limited warranty is valid for 12 months from the date of purchase. During this time, the manufacturer declares that it will replace or repair defective products. The date of purchase corresponds to the delivery date if the product was purchased directly from us, or the date of installation if you purchased the device via a specialist retail partner.

All repairs to products which are covered by the warranty must be carried out by the manufacturer or by a specialist retail partner. All warranty claims expire if the repairs were unauthorised.

15.2 Warranty Exemption

The warranty does not cover damage which was caused by the following:

- Not complying with the storage or transportation conditions.
- Improper use, servicing or repair.
- Use of spare parts other than the original spare parts or spare parts approved by the manufacturer.
- Any technical changes to the device.
- Overvoltage or undervoltage.
- Installing and operating third-party software which has not been approved by the manufacturer.
- Connecting third-party devices which has not been approved by the manufacturer.
- Operating the device outside of the valid environmental conditions.

15.3 Packaging and Shipping

To avoid damage during transport, devices must be sent along with the warranty claim in the original packaging.
This also applies for defective devices being repaired.
Transport damage arising from improper packing is the responsibility of the customer. In addition, insurance during transport is recommended. Claims due to loss or damage must be made by the shipper.

16 Authorised Specialist Retail Partner

You can reach your responsible specialist retail partner via a contact form of the manufacturer
www.geratherm-respiratory.com/login/

see depositors

Attachment – Declaration of Conformity

The Ergostik declaration of conformity is enclosed with each device by the manufacturer.